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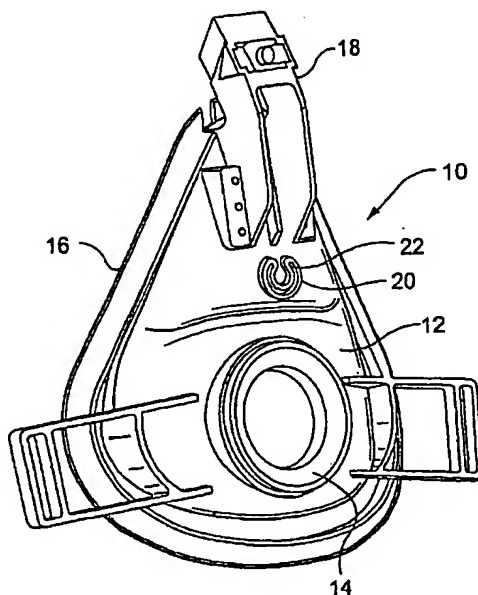
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(54) Title: RESPIRATORY MASK HAVING GAS WASHOUT VENT AND METHOD FOR MAKING THE MASK



(57) Abstract: A washout vent (20) for a mask for use with a system for supplying breathable gas pressurized above atmospheric pressure to an airway of a mammal. The washout vent (20) includes a vent orifice (22) adapted for gas washout. The orifice (22) includes one or more features that contribute to noise reduction, such as a channel (26) with converging walls towards atmosphere, and/or a channel (26) having one or more walls provided with surface treatment and/or contouring, such as roughening and/or scalloped portions.

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## RESPIRATORY MASK HAVING GAS WASHOUT VENT AND METHOD FOR MAKING THE MASK

### CROSS-REFERENCE TO APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application Nos. 60/643,114, filed January 12, 2005, and 60/714,910, filed September 8, 2005, each of which is incorporated herein by reference in its entirety.

[0002] Also, U.S. Provisional Application No. 60/590,338, filed 23 July 2004, by Fu and Saada, is incorporated herein by reference in its entirety.

### BACKGROUND OF THE INVENTION

[0003] Treatment of sleep disordered breathing (SDB), such as obstructive sleep apnea (OSA), by continuous positive airway pressure (CPAP) flow generator systems involves the continuous delivery of air (or other breathable gas) pressurized above atmospheric pressure to the airways of a human or other mammalian patient via a conduit and a mask. Typically, the mask fits over the mouth and/or nose of the patient. Pressurized air flows to the mask and to the airways of the patient via the nose and/or mouth. As the patient exhales, carbon dioxide gas may collect in the mask. A washout vent in the mask or conduit discharges the exhaled gas from the mask atmosphere.

[0004] The washout vent is normally located in the mask or near the mask in the gas delivery conduit coupled to the mask. The washout of gas through the vent to the atmosphere removes exhaled gases to prevent carbon dioxide build-up, and hence "rebreathing", which represent a health risk to the mask wearer. Adequate gas washout is achieved by selecting a vent size and configuration that allows a minimum safe washout flow at a low operating

CPAP pressure, which typically can be as low as 4 cm H<sub>2</sub>O for adults and 2 cm H<sub>2</sub>O for children.

[0005] Noise is a significant issue in CPAP treatment for the patient and/or the patient's bed partner. Excessive noise can lead to patients being non-compliant with the CPAP therapy. One source of noise is the exhaust through the vent in the mask or conduit. The flow of gas through the vent creates noise as it exits to and interacts with the atmosphere. Noise can adversely affect patient and bed-partner comfort, depending on both the magnitude and character of the noise. Further, bi-level gas delivery regimes tend to generate more noise than do constant level gas delivery regimes. This is thought to be due to the extra turbulence created by the gas accelerating and decelerating as it cycles between relatively low and relatively high pressures in the bi-level gas delivery systems.

[0006] The washout vents may offer a generally fixed impedance to air flow (for example having a generally unchanging geometry with time) or a variable impedance. In a fixed vent design, the vent flow increases with mask pressure, such that the vent flow may be adequate at a low pressure and excessive at high pressure. The variations in flow through fixed vent can lead to noise. Fixed vents are generally simple and inexpensive to make and operate. A variable vent design could provide a constant or near constant vent flow across a range of mask pressures having the advantage that noise will not increase as mask pressure is increased. This may lead to lower vent flow at high pressures which may in turn lead to less noise. However variable vents suffer from difficulties in manufacture, assembly, consistency, cleaning and usability.

[0007] Fixed gas vents are known that have relatively low noise levels, which levels may be as low as 30dBA at a therapy (mask) pressure of 12cm H<sub>2</sub>O. Such vents include, for example, the ResMed MIRAGE™ mask (disclosed in US Patent 6,561,190), the ResMed ULTRA MIRAGE™ mask (disclosed in US Patent 6,691,707), the ResMed VISTA™ mask

(disclosed in US Published Patent application 2003/0196657), the ResMed ACTIVA™ mask that includes an elbow with a vent (disclosed in International Patent Application PCT/AU03/01162 published as WO 2004/022147) and the ResMed MERIDIAN™ disposable nasal mask that includes an elbow incorporating a vent (disclosed in International Patent Application PCT/AU2004/000563). The contents of all of these patents and patent applications are incorporated herein by reference in their entireties.

[0008] Various quiet vents are known that provide noise levels generally in the range of 25dBA or less which makes the vent noise difficult to distinguish from transmitted flow generator noise or general background noise. Examples of quiet vents are disclosed in US Patent 6,581,594 and the Weinmann sintered vent. At least the sintered vent is believed to suffer from poor manufacturability, durability, blockage, humidification, sterility/bacterial growth, and/or cleanability.

[0009] There is a long felt and continuing need for quiet gas vents for masks and conduits, that are relatively inexpensive, simple in their construction and easy to maintain. Reducing the noise of gas being exhausted from a mask or conduit can significantly improve the user friendliness of the CPAP treatment. Providing a simple and easy to use low-noise vent can reduce the cost of CPAP treatments and thereby assist in making the treatment more affordable to patients suffering from SDB.

#### SUMMARY OF THE INVENTION

[0010] One aspect of the invention is to provide a vent assembly for quiet washout of exhaled gas, which may be accomplished, e.g., using one or more surface characteristics, such as surface treatment, e.g., roughening, and/or surface contouring, e.g., scalloped portions that may be provided to one or more walls of one or more slotted vent apertures. The aperture may take the form of a single arcuate or semi-circular slot having opposed walls that may

subtly converge towards and/or diverge from one another in the direction of flow. The slot may take the form of a linear slot and the walls may be parallel to or non-tapering relative to one another in other embodiments.

[0011] In another aspect of the invention, a mask includes a vent assembly having an aperture including one or more of the following features: a curvilinear shape, a slot, converging and/or diverging side walls, surface roughness, scalloping/crenations, a rounded or bell-shaped inlet, a development length and/or exit (or minimal) width designed to develop appropriate gas washout, and/or material properties (e.g., density, thickness) to promote quiet exiting of gas.

[0012] A particularly preferred embodiment includes a mask with a vent assembly including an aperture including one or more of the following features: a curvilinear shape, a rounded or bell-shaped inlet and/or a development length and/or exit (or minimal) width designed to develop appropriate gas washout.

[0013] The invention may be embodied as a washout vent for a mask for use with a system for supplying breathable gas pressurized above atmospheric pressure to an airway of a mammal, the washout vent comprising: a vent orifice adapted for gas washout, wherein said orifice at least partially defines or completes a conic section, e.g., a circle, ellipse, parabola, hyperbola, etc. In one preferred example, the orifice completes about 220°-300°, and preferably 270°, of a circle or an ellipse.

[0014] The vent assembly may comprise a single orifice having a shape of a horse-shoe, ellipse, spiral, curved, straight crescent(s), semi-circle, curvilinear slot portions thereof, or any combination of the above. The orifice may be a plurality of orifices arranged on the mask or a removable vent assembly insert. Further, the vent comprises a channel between the orifice and the mask shell, wherein the channel has a depth at least as thick as a thickness of the mask and preferably at least four times larger than a width of the orifice. The sidewalls of

the channel may converge towards each other and may have a coarse or roughened surface treatment and/or a scalloped surface, to reduce the noise of the washout gas exhausting through the orifice.

[0015] In another embodiment, the invention may comprise a vent assembly for washout of gas from a mask used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal patient, said vent assembly comprising: an orifice in fluid communication with an interior of the mask, and a solid section at least partially surrounded by the orifice. The vent assembly may be an insert formed from an elastomeric material that is substantially softer and more flexible than the hard plastic mask shell, and said insert is selectively and repeatably attachable to and detachable from the mask. The vent assembly may be substantially crescent-shaped and includes one or more orifices therethrough. The orifice may have a conic shape e.g., selected from a group consisting of a horse-shoe, crescent, a 270 degree semi-circle and a curvilinear slot, etc. Further, the vent assembly comprises a channel extending between the orifice and the interior of the mask, and the channel comprises sidewalls surface treatments, such as a coarse or roughened surface, and the sidewalls may be scalloped.

[0016] Another aspect of the invention relates to a washout vent for a mask for use with a system for supplying breathable gas pressurized above atmospheric pressure to an airway of a mammal. The washout vent includes a vent orifice adapted for gas washout. The orifice includes opposed edges or side walls. A channel is provided between an orifice exit and an interior surface of the mask. The orifice has a curved configuration including a diameter in the range of 4-20 mm extending through an arc in the range of 130-150 degrees. The channel includes a width in the range of 0.5-1.0 mm, a depth in the range of 2.5-3.5 mm, an inlet radius in the range of 1-2 mm, and a draft angle in the range of 3-7 mm.

[0017] Yet another aspect of the invention relates to a mask assembly including a mask frame and two washout vents provided to the mask frame. Each of the vents includes an elongated, curved vent orifice adapted for gas washout.

[0018] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0020] FIGURES 1 and 2 show respectively a front isometric view and rear isometric view of a mask frame incorporating a vent in accordance with a first embodiment of the invention.

[0021] FIGURES 3, 4 and 5 show respectively a front plan view (viewed from the mask exterior), a front isometric view and a rear isometric view (viewed from mask interior) of the vent shown in Figures 1 and 2.

[0022] FIGURES 6 and 7 are cross-sectional views of the vent taken along lines 6-6 and 7-7 respectively of Figure 3.

[0023] FIGURES 8 to 10 show respectively a front plan view (viewed from mask exterior), a front isometric view and a rear isometric view (viewed from mask interior) of a second embodiment of the vent.

[0024] FIGURES 11 and 12 are rear plan and rear isometric enlarged views showing a scalloped surface treatment and crenated outlet edge of the second embodiment of the vent.

[0025] FIGURE 11A is a schematic view showing exemplary dimensions and geometry of a vent orifice according to an embodiment of the present invention.

[0026] FIGURES 13 and 14 are front plan views of alternative embodiments of the vent.

[0027] FIGURE 15 is a front view of a vent on an alternative mask.

[0028] FIGURE 16 is a exploded view of an alternative end cap for the mask shown in Figure 15.

[0029] FIGURE 17 is a front isometric view of a swivel elbow with a vent.

[0030] FIGURE 18 is a front isometric view of the gas conduit shown in Figure 17 without a vent shield.

[0031] FIGURE 19 is a rear isometric view of the vent shield for the conduit shown in Figure 17.

[0032] FIGURES 20 and 21 illustrate a vent assembly according to yet another embodiment of the present invention.

[0033] FIGURE 22 illustrates a vent assembly according to still another embodiment of the present invention.

[0034] FIGURES 23-25 illustrate still another embodiment according to the present invention.

[0035] FIGURES 26 and 27 illustrate yet another vent assembly according to an embodiment of the present invention.

[0036] FIGURES 28-34 illustrate additional vent orifices having shapes according to embodiments of the present invention.

[0037] FIGURE 35 is a front plan view of a mask frame including washout vents according to an embodiment of the present invention.

[0038] FIGURE 36 is a cross-sectional view of a vent a taken along line 36-36 of FIGURE 35 and showing dimensions of an embodiment.

[0039] FIGURE 37 is an enlarged plan view of a vent taken from FIGURE 35 and showing dimensions of an embodiment.



[0040] FIGURES 38-44 illustrate alternative embodiments for orienting two vents on a mask frame.

#### DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

##### 1. First Embodiment of Gas Washout Vent

[0041] FIGURES 1 and 2 show a mask frame 10 for use with a system for supplying breathable gas pressurized above atmospheric pressure to an airway(s) of a human or other mammal, e.g., a CPAP or other non-invasive positive pressure delivery system. The mask frame includes a rigid plastic shell 12 having an air inlet tube aperture 14 for connection to a supply conduit to communicate breathable gas from a flow generator (not shown) to the airways of the mask wearer. The mask shell 12 includes a rim 16 which supports a flexible sealing membrane (not shown) that provides a gas tight seal between the face of the patient and the interior volume 17 of the shell 12. The shell 12 includes a support 18 for connecting the mask 10 to a forehead support (not shown) which includes, e.g., a T-Bar having slotted connectors for receiving headgear straps that retain the mask over the nose and/or mouth while the patient sleeps. The mask frame may be molded from a generally rigid material such as polycarbonate.

[0042] A vent 20 on the mask includes an orifice 22 for gas washout. The orifice is partly defined by channel 26 (Fig. 6) that provides a flow passage from the interior 17 of the mask to the atmosphere. The orifice may in plan view have a conic shape, e.g., opposed walls or edges defining the orifice may be formed in any shape that can be defined by a complete or partial cross-section taken through a cone or a partial conic section. For example, the orifice may be in the form of a circle, hyperbola, ellipse, parabola, semi-circle, or portions thereof. In addition, the opposed walls or edges of the orifice may define other shapes, such as a "C", horse-shoe, crescent, a pair of opposing crescents, sinusoidal curves, a series of convex and

concave segments, spiral, portions or sections thereof, or other curvilinear or even linear shapes.

[0043] In another sense, the orifice is provided on a solid section 32 of the mask that forms a peninsula that is partially surrounded by the orifice. The solid section may be a plate with a bridge to the mask. The solid section may be in a plane common to the mask and recessed with respect to the orifice or the solid section may be recessed relative to the remainder of the mask such that the vent aperture is flush with the outside of the mask.

[0044] A common characteristic of one embodiment of the curvilinear or linear orifice is that the orifice has a length (L – Fig. 3) substantially greater than its characteristic width (W). For example, the length (L) may be at least five (5) times the width (W) of the orifice, and the length may be preferably 10 to 20 times the width. This ratio may in certain applications be less than five and greater than 20. If the orifice is a plurality of circle segments (or other arrangement of segments) the combined length (L) of the segments is substantially greater than their average width. Further, the area of the orifice, e.g., length times width (depending on the shape of the orifice), is preferably about  $15\text{mm}^2$  and may be in a range of, for example,  $5\text{mm}^2$  to  $25\text{mm}^2$ . The smallest cross-sectional area of the orifice, which may occur anywhere along the length of the channel or orifice, defines the resistance of the vent.

[0045] As shown in FIGURES 3, 4 and 5, the orifice 22 may be formed at the apex of a raised ridge 24 extending outward from the mask shell or at the bottom of a groove formed in the shell. In the embodiment shown in Figures 1 to 5, the ridge 24 in plan view is a three-quarters ( $3/4$ ) section of a circle, i.e., it accommodates for and matches the shape of the orifice.

[0046] It is thought that an orifice of the configuration shown in Figures 3-5 helps reduce noise, at least in part, because the jetted air encounters, on exit, air that is not necessarily stagnant, but is moving somewhat due to neighboring sections of the orifice that promote the

movement of such jetted air in the exit direction. Stated differently, the curved nature of the slot, especially one that "folds over" on itself, in the form of a curvilinear section, helps minimize the difference in velocity between the jetted air and the surrounding environmental air.

[0047] The ridge and/or its orifice may be segmented to form, for example, an array of circle segments or a pair of opposite crescent ridges. The orifice, when in the form of a semi-circular shape, defines a peninsula 32 that connects to and is formed as part of the mask. The ridge or groove may have a shape similar but wider than the shape of the orifice.

[0048] The diameter (D) (see Fig. 6) of the circle formed by the orifice is preferably about 6-8mm, preferably about 6mm, and may be in a range of 4mm to 20mm. The diameter (D) of the semi-circular orifice may be determined based on the desired surface area, e.g.,  $15\text{mm}^2$ , of the orifice. Further, the diameter (D) may vary beyond the suggested 4mm to 20mm range depending on the application.

[0049] The inner surfaces 28 of the orifice 22 define, or are defined by, a channel 26 extending from the interior 17 of the mask shell to the exit of the orifice 22. The channel 26 may be curvilinear, e.g., horse-shoe shaped, and have a shape similar to the exit of the orifice. In the illustrated embodiment, a gap (W) of the orifice 26 generally narrows (converges) from the mask interior surface to the exit of the orifice. However, the orifice may also diverge in the direction of flow, or the orifice may have a complex shape such that it diverges in one section, and converges in another section of the orifice, in the direction of the flow of gas. In the illustrated embodiment, the gap of the orifice is open to the interior 17 of the mask shell. The gap between inside surfaces 28 of the channel walls may be approximately 0.5mm to 1.0 mm, and preferably 0.75mm at its narrowest width. The slope of each inner surface may be a draft angle (DA) of  $5^\circ$  from an axis extending through the channel. While a draft angle of  $5^\circ$  is preferred, other draft angles are possible such as angles ranging from 3 to 7 degrees.

[0050] The channel 26 may have a depth (DD) approximately four times the narrowest width of the channel gap (W). The channel depth (DD) is a distance from an inside surface of the mask shell to the exit of the orifice. In a preferred form, the channel depth is 3mm and the gap (W) is .75mm. The channel depth is generally greater than the thickness (T) of the mask shell, such that the vent and orifice protrude from the surface of the shell. The mask may have a thickness of 1.0mm. The ratio of the channel depth (DD) to the width (W) of the orifice is preferably 4.0 (e.g., 3.0mm/0.75mm), and may be in a range of 2 to 100.

## 2. Second Embodiment of Gas Washout Vent

[0051] FIGURES 8 to 11 show a channel 26 in which the sidewalls 28 have surfaces shaped and/or treated to increase turbulence of air exhausting from the channel and into the atmosphere. This has the effect of quickly mixing the vented air with the air from atmosphere, to thereby rapidly reduce the velocity of vented air – which is thought to reduce noise. At least a portion of the interior surfaces 28 of the channel may have a shaped surface, for example, being scalloped with crenated edges, and/or a treated surface, e.g., a coarse surface treatment such as a roughened or scaled surface. One example of roughening may be in the order of 100-200 microns. The surface treatment may be applied to the inner surfaces of the channel near the orifice. Scaled refers to a surface treatment that appears similar to the scales on a fish, such as a shark.

[0052] In one embodiment, the surface contouring or shaping may include a series of scalloped grooves 34, e.g., 10-30 grooves, and preferably about 18 grooves in the illustrated example, in each of the interior surfaces of the channel as are shown in Figures 8 to 12. While the grooves 34 are illustrated to have the same dimensions, the size of the grooves could alternate between larger grooves and smaller grooves, or each of the grooves could have a different size. Further, at the channel inlet, the side walls may be smooth and not

scalloped. As shown in Figures 6, 7 and 12, the base of the interior walls 28 is well rounded or bell-shaped to facilitate passage of air. Smooth inner surfaces 28 may extend at least down to one-half the depth of the channel.

[0053] Conceptually, the shape of the scalloped grooves may be formed by cutting with cylindrical drill bits that have a diameter wider than the orifice (W) and narrower than the widest portion of the channel. Drilling the sloped channel sidewalls with cylindrical drill bits forms scalloped grooves beginning at the narrow outlet of the channel and extending inward along a portion of the walls. Drilling the grooves also yields parabolic edges along the inner walls of the vent. Alternatively, and preferably, the scalloped grooves may be formed during molding by vent molds that include scalloped ridges on the walls of the mold corresponding to the vent channel. It should be noted that scalloping can be provided on side walls even if they do not taper, conceptually by using a conical drill bit and drilling from the exit of the orifice inward.

[0054] The outlet edges of the channel, such as surrounding the orifice, may be crenated. The outlet edge 35 of the channel may be a sequence of relatively straight segments (S') and interleaving crenated segments (S), e.g., elliptical or rounded segments. The alternating straight and crenated segments of the channel edge promote mixing of the jet stream exiting the vent with stagnant air just downstream of the channel outlet. While the edge segments (S' and S) are shown as being relatively uniform, the segments may vary in length and depth along the edge of the channel. In addition, the width (W') of the channel is smaller than the width (W) of the channel for the scalloped portions to be formed. Figure 11A is a schematic view showing the relative positions of these dimensions.

### 3. Third Embodiment of Gas Washout Vent

[0055] FIGURE 13 is a front plan view of another embodiment of a vent orifice 45 having channel sidewalls 44 that have a coarse surface treatment 46 at least near the edge of the channel at the orifice preferably at the exit edge. The coarse surface is believed to increase the turbulence of air flowing along the sidewalls of the channel. The orifice 45 and the associated channel (which may be a ridge extending outward from a mask shell 12 or a groove extending into the shell) has a curvilinear shape that has a serpentine sequence of convex and concave curve segments. The coarse surface treatment may be separate from or combined with the scalloped grooves on the channel sidewalls. The interior walls 44 of the channel may be made coarse 46 by, for example, sandblasting the portion of the mold corresponding to the vent channel.

[0056] To mold the vent (either as a separate vent or vent integral with the mask) a mold is first formed of the vent, wherein the mold comprises a ridge corresponding to a channel and orifice of the assembly. The geometry of the mold may be cut to include scalloping features, and the surface of the mold may be treated, e.g., via sand blasting, to produce the desired level of surface roughness on the interior surfaces of the vent. The surface treatment or contouring is preferably applied to the mold sidewalls on opposites sides of the mold section corresponding to the vent channel and particularly to the exit edge of the vent (orifice). A plastic material (e.g., polycarbonate) is injected into the mold to form a molded vent assembly having a channel that possesses the scalloped and/or surface roughness of the mold.

### 4. Fourth Embodiment of Gas Washout Vent

[0057] FIGURE 14 is a plan view of alternative orifice 36 and a removable elastomeric insert 40 that fits into an aperture 42 in a mask shell. Vent inserts are known and disclosed in, for example, US Patent Nos. 6,561,190 and 6,561,191 and US Patent Application Publication

2003/0079751, each incorporated by reference in its entirety. Whereas vent inserts typically have had an array of small circular orifices, the orifice 36 in Figure 14 is an extended curvilinear slot. Alternatively, or in addition, the orifice 36 may include a channel as described above with a predetermined draft angle, roughening, and/or one or more scalloped portions. The vent insert in Figure 14 may be identical in its outside shape to an existing insert and may fit into existing mask shells. The curvilinear orifice in the replaceable vent 40 allows for curvilinear slots (such as those shown in this disclosure) to be used on existing mask assemblies. The insert 42 may be formed of a flexible polymer, e.g., Santoprene™. The inserts 42 are removable for replacement and cleaning.

#### 5. Gas Washout Vent On Alternative Mask

[0058] FIGURE 15 is a perspective view of a mask 50 that includes nozzles 52 that interface with the nares of the patient. Similar masks are disclosed in, for example, Figures 117 and 130 of US Patent Application Publication No. 2004/0226566, which publication is incorporated by reference in its entirety. Whereas washout vents conventionally have been an array of circular openings, the present mask includes one or more curvilinear vents 54 including one or more of the features described above in relation to Figures 3-12, e.g., a slot with converging walls, optionally provided with surface contouring or surface treatment, e.g., scalloped portions and/or roughening. The illustrated vent assembly has one or more elongated orifices that are believed to operate quieter than do the conventional circular vent orifices.

[0059] FIGURE 16 is a partial exploded view of a yoke, frame, sealing ring and end cap assembly 56 for the mask shown in Figure 15. The end cap 58 shown in Figure 16 has a curvilinear washout vent 60. Positioning a single large orifice vent on the end cap avoids a need for a plurality of vents on another portion of the mask such as the cushion.

#### 6. Swivel Elbow With Gas Washout Vent

[0060] FIGURES 17, 18 and 19 are views of an air inlet conduit 70 that has an air inlet 72 and an air outlet 74, similar to that shown in US Patent 6,691,707, the entirety of which is incorporated by reference. A hose (not shown) fits to the inlet to provide pressurized air from a blower or other source of air. The outlet 74 fits to an aperture in the mask, such as aperture 14 in the mask shown in Figure 1. An elbow in the conduit 70 includes a vent shield 76 that covers at least one vent orifice 78 (shown in Figure 15) which may be a series of curvilinear slot orifices. The orifices exhaust washout gases into a gap between an outer surface 80 of the conduit and an inner surface 82 (Fig 16) of the shield. A coarse surface treatment 84 may be applied to the inner surface 82 and outer surface 80 in the area corresponding to the gap, especially near the outlet to atmosphere. The gap receives washout gas from the vents 78 and exhaust the gas at an end 86 of the shield. Scalloped grooves 88 may be formed on the surfaces 80, 82, such as near the end 86 of the shield. The grooves form crenated edges at the outlet of the gap. These edges promote mixing of the washout gas exhausting from the gap with stagnant atmospheric air, which is thought to rapidly decrease the velocity difference (shear rate) between the atmosphere, reducing exhausted gas and the attendant noise thereof.

[0061] FIGURES 20 and 21 illustrate another embodiment of the present invention which is very similar to the embodiment of FIGURES 17-19. However, only the cap 76 is provided with surface treatment (e.g., scalloping and/or roughening) on its inside surface.

#### 7. Mask Assembly With Vent Assembly

[0062] FIGURE 22 illustrates another embodiment of the invention showing a mask assembly adapted to include a vent assembly 200 having one or more surface treatments (scallop/roughening) that may be applied to a single curvilinear aperture 202 provided on



the vent cover. More details of this mask assembly are disclosed in U.S. Patent Application No. 10/655,621 filed September 5, 2003, incorporated herein by reference in its entirety.

8. Alternative Mask Assembly With Vent Assembly

[0063] FIGURES 23-25 illustrate a mask assembly including a vent assembly 300 according to yet another embodiment of the present invention. Vent assembly 300 is part of a ResMed mask more fully described in U.S. Patent No. 6,112,746, incorporated herein by reference in its entirety. The mask assembly may include one or more attributes of the vent assembly described in relation to FIGURES 3-12.

9. Alternative Mask Assembly With Vent Assembly

[0064] FIGURES 26 and 27 illustrate a portion of a mask assembly 400 as described in EP 0 985 430 A2, incorporated herein by reference in its entirety. The mask assembly includes a vent assembly 404 to exhaust exhaled gas to atmosphere, e.g., via path 406 defined by an interior wall 408 and an exterior wall 410. Each wall 408, 410 may include one or more surface treatments, e.g., scalloping and/or roughening, as described above.

10. Vent Orifice Shapes

[0065] FIGURES 28-34 illustrate further orifice shapes according to the present invention. In each embodiment, the total open area of the orifice is selected to address adequate gas washout, as described above. FIGURE 28 is a  $\frac{3}{4}$  ellipse, as compared to the  $\frac{3}{4}$  circle in FIGURE 29. FIGURE 30 shows two parts of an ellipse having areas A1 and A2 which combined form a total Area ( $A_{TOTAL}$ ). FIGURE 31 shows a generally curvilinear orifice, while FIGURE 32 shows a spiral shaped orifice having multiple component radii ranging from R1 to R2. FIGURE 33 illustrates an orifice with curved and straight sections

(delineated by section lines), while FIGURE 34 shows an "S"-shaped orifice having radii R1 and R2 that are equal.

#### 11. Mask Frame with Two Curved Washout Vents

[0066] FIGURES 35-37 illustrate a mask frame 510 including two curved washout vents 520 according to an embodiment of the present invention. The vents 520 have a generally similar vent structure to the vents 20 described above in relation to Figures 1-7. However, the two vents 520 are oriented on the mask frame 520 in a particular manner. Also, the vents 520 include specific dimensions for an embodiment.

[0067] Specifically, each vent 520 includes a diameter of 7.7 mm extending through a 142 degree arc (see Figure 37). This arrangement improves the strength of the vent material when compared to a larger arc. As shown in Figure 36, each vent 520 also has a width of 0.85 mm, a depth of 3 mm, an inlet radius of 1.5 mm, and a draft angle of 6 degrees. Although specific dimensions of the vents 520 are shown in Figures 36 and 37, it is to be understood that these dimensions are merely exemplary and other dimensions are possible depending on application. For example, the diameter may be in the range of 4-20 mm, preferably 6-8 mm, extending through an arc in the range of 130-150 degrees. The width may be in the range of 0.5-1.0 mm, the depth may be in the range of 2.5-3.5 mm, the inlet radius may be in the range of 1-2 mm, and the draft angle may be in the range of 3-7 mm. Also, the vents 520 may include one or more additional features as described above, e.g., surface contouring or surface treatment. Further, the vents 520 may include other orifice shapes such as those described in Figures 28-34.

[0068] As shown in Figure 35, two vents 520 are provided to the mask frame 510. As illustrated, the mask frame 510 includes a receiver 562 adapted to receive a forehead support. The two vents 520 are positioned on the mask frame 510 between spaced-apart side walls 564

of the receiver 562. In addition, the two vents 520 are positioned end to end with a small gap therebetween so that they together define a generally reverse-S shape. Further, the two vents 520 are oriented such that a line L extending through a center of each vent 520 is generally perpendicular to a longitudinal axis A of the mask frame 510.

[0069] This vent arrangement on the mask frame 510 allows the width of each vent 520 to be thinner than if just one vent were used. Also, the two vents 520 may be quieter than one vent, which may be due to the thinner width of each vent and/or more vent perimeter per open area. In addition, two vents 520 may reduce the lateral space required on the frame 510. However, it is to be understood that any suitable number of vents 520 may be provided to the frame 510, e.g., one vent or more than two vents. Also, the vents 520 may be oriented on the mask frame 510 in other suitable manners.

[0070] Figs. 38-44 illustrate several alternative embodiments for orienting two vents 520 on the mask frame. For example, the two vents 520 may be vertically aligned with both vents curved downwardly (see Fig. 38) or both vents curved upwardly (see Fig. 39). The two vents 520 may be horizontally aligned with the vents curved towards one another (see Fig. 40) or the vents curved away from one another (see Fig. 41). The two vents 520 may be vertically offset with the vents curved towards one another (see Fig. 42). The two vents 520 may be positioned end to end with a small overlap (see Fig. 43). Also, the two vents 520 may be positioned end to end with small gap therebetween so that they together define a generally S shape (see Fig. 44). It is noted that additional vent configurations may be created by mirroring, rotating, and/or scaling the vent geometry, e.g., see Figs. 28-34.

[0071] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to

cover various modifications and equivalent arrangements included within the spirit and scope of the invention. For example, while the vent assemblies described above may be used in the field of treating patients with sleep disordered breathing, they may also be beneficial to the field of respirators or ventilators in general, e.g., for use in treatment of other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.), or they may be used in any breathing apparatus for use with patients or non-patients when venting in a quiet cost effective manner is desirable.

## WHAT IS CLAIMED IS:

1. A washout vent for a mask for use with a system for supplying breathable gas pressurized above atmospheric pressure to an airway of a mammal, the washout vent comprising:

a vent orifice adapted for gas washout, wherein said orifice includes opposed edges or side walls defining at least a portion of a conic section.

2. A vent as in claim 1 wherein orifice defines a solid section of the vent in the form of a peninsula.

3. A vent as in any of claims 1 or 2 wherein the vent orifice comprises a semi-circular slot extending approximately 270 degrees.

4. A vent as in any of claims 1 to 3 wherein the conic section defines a hyperbola, parabola, ellipse, circle, any portion thereof, or any combination thereof.

5. A vent as in any of claims 1 to 4 wherein the vent orifice is at an apex of a ridge on the mask.

6. A vent as in claim 5 wherein the orifice exit is in a plane offset from the mask.

7. A vent as in claim 6 wherein the orifice exit is in a plane common to the mask.

8. A vent as in claim 5 wherein the ridge is curvilinear in length.

9. A vent as in any of claims 1 to 8 wherein the vent is provided in an insert attachable to the mask.

10. A vent as in any of claims 1 to 9 wherein the orifice is substantially crescent-shaped.

11. A vent as in any of claims 1 to 10 wherein the orifice is one of a plurality of orifices therethrough.

12. A vent as in any of claims 1 to 10 wherein the orifice has a horse-shoe shape.

13. A vent as in any of claims 1 to 10 wherein the orifice comprises convex and concave segments.

14. A vent as in any of claims 1 to 10 wherein the orifice comprises a plurality of semi-circular segments.

15. A vent as in any of claims 1 to 10 wherein the orifice is a partial circle and partially surrounds a peninsula portion of the mask.

16. A vent as in any of claims 1 to 15 further comprising a channel between the orifice exit and an interior surface of the mask.

17. A vent as in claim 16 wherein the channel has a depth at least as thick as a thickness of the mask.

18. A vent as in claim 16 wherein the channel has a depth at least five times larger than a width of the orifice exit or minimum.

19. A vent as in claim 16 wherein the channel comprises sloping side walls.

20. A vent as in claim 16 wherein the slide walls have a slope of 5 degrees from an axis of the channel.

21. A vent as in claim 16 wherein the side walls have a slope in a range of 3 degrees to 7 degrees from an axis of the channel.

22. A vent as in any of claims 1 to 21 wherein the channel extends outwardly from an outside surface of the mask and the channel is defined by interior walls of a ridge on the mask.

23. A vent as in claim 1 wherein the channel extends inwardly of an inside surface of the mask and the channel is defined by interior walls of a groove in the mask.

24. A vent as in any of claims 16 to 23 wherein the channel has sidewalls comprising a surface treatment and/or contouring.

25. A vent as in claim 24 wherein the surface treatment is applied to a section of the sidewalls adjacent the orifice.

26. A vent as in any of claims 24 to 25 wherein the surface treatment comprises a roughened surface.

27. A vent as in any of claims 24 to 26 wherein the surface contouring comprises scalloping.

28. A vent as in claim 27 wherein the scalloping comprises scalloped sections aligned orthogonally to the orifice.

29. A vent assembly for washout of gas from a mask used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal patient, said vent assembly comprising:

a solid section; and

an elongated, curvilinear orifice formed in the solid section and in fluid communication with an interior of the mask.

30. A vent assembly as in claim 29 wherein the solid section is a peninsula section of the mask.

31. A vent assembly as in claim 29 wherein the solid section is a peninsula section of the vent assembly.

32. A vent assembly as in claim 29 wherein the vent assembly comprises an insert formed from an elastomeric material and said insert is attachable to the mask.



33. A vent assembly as in claim 32 wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

34. A vent assembly as in claim 29 wherein the orifice has a shape selected from a group consisting of a horse-shoe, crescent, a 270 degree semi-circle and a curvilinear slot.

35. A vent assembly as in any of claims 29 to 33 further comprising a channel extending between the orifice and the interior of the mask, and the channel comprises sidewalls having a surface treatment and/or contouring.

36. A vent assembly as in claim 35 wherein the surface treatment is applied to a section of the sidewalls adjacent the orifice.

37. A vent as in any of claims 35 to 36 wherein the surface treatment comprises a roughened surface.

38. A vent as in any of claims 35 to 36 wherein the surface contouring comprises scalloping.

39. A vent as in claim 38 wherein the scalloping comprises scalloped sections aligned orthogonally to the orifice.

40. A method for forming a vent assembly in a mask for use with a system for supplying breathable gas pressurized above atmospheric pressure to an airway of a mammalian patient, the method comprising:

- a) forming a mold of the vent assembly, wherein the mold comprises a ridge defining a channel and an elongated orifice having a non-circular cross section,
- b) applying a surface treatment and/or contouring to at least one interior sidewall of the ridge, and
- c) injecting a material into the mold to form a molded vent assembly having a channel.

41. A method as in claim 40 wherein the surface treatment comprises sandblasting the sidewall to roughen the sidewall.

42. A method as in any one of claims 40-41, wherein the surface contouring comprises is a scalloped grooves on the sidewall.

43. A method as in claim 40 wherein the surface treatment and/or contouring is applied to a section of the sidewall adjacent a narrow portion of the ridge.

44. A vent assembly for washout of gas from a mask used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal patient, said vent assembly comprising:

an orifice in fluid communication with an interior of the mask, and

a channel between the orifice and an interior section of the mask, wherein the channel has scalloping along a sidewall and said sidewall has crenated edges at an outlet of the channel.

45. A vent assembly as in claim 44 wherein the scalloping comprises scalloped sections aligned orthogonally to the orifice.

46. A washout vent for a mask for use with a system for supplying breathable gas pressurized above atmospheric pressure to an airway of a mammal, the washout vent comprising:

a vent orifice adapted for gas washout, said orifice including opposed edges or side walls; and

a channel between an orifice exit and an interior surface of the mask,

wherein the orifice has a curved configuration including a diameter in the range of 4-20 mm extending through an arc in the range of 130-150 degrees, and

wherein the channel includes a width in the range of 0.5-1.0 mm, a depth in the range of 2.5-3.5 mm, an inlet radius in the range of 1-2 mm, and a draft angle in the range of 3-7 mm.

47. A washout vent as claimed in claim 46, wherein the orifice includes a diameter of 7.7 mm extending through a 142° arc, and the channel includes a width of 0.85 mm, a depth of 3 mm, an inlet radius of 1.5 mm, and a draft angle of 6°.

48. A mask assembly including a mask frame and at least one washout vent according to any one of claims 46-47 provided to the mask frame.

49. The mask assembly according to claim 48, wherein two washout vents are provided to the mask frame.

50. A mask assembly, comprising:  
a mask frame; and  
two washout vents provided to the mask frame, each of the vents including an elongated, curved vent orifice adapted for gas washout.
51. The mask assembly according to claim 50, wherein the mask frame includes a receiver adapted to receive a forehead support, and the two vents are positioned on the mask frame between spaced-apart side walls of the receiver.
52. The mask assembly according to any one of claims 50-51, wherein the two vents are positioned end to end so that they together define a generally reverse-S shape.
53. The mask assembly according to any one of claims 50-52, wherein the two vents are oriented such that a line extending through a center of each vent is generally perpendicular to a longitudinal axis of the mask frame.
54. The mask assembly according to claim 50, wherein the two vents are vertically aligned.
55. The mask assembly according to claim 54, wherein both vents curve downwardly towards a bottom of the frame.
56. The mask assembly according to claim 54, wherein both vents curve upwardly towards a top of the frame.

57. The mask assembly according to claim 50, wherein the two vents are horizontally aligned.
58. The mask assembly according to claim 57, wherein the vents curve towards one another.
59. The mask assembly according to claim 57, wherein the vents curve away from one another.
60. The mask assembly according to claim 50, wherein the two vents are vertically offset and the two vents curve towards one another.
61. The mask assembly according to claim 50, wherein the two vents are positioned end to end with a small overlap.
62. The mask assembly according to claim 50, wherein the two vents are positioned end to end with small gap therebetween so that they together define a generally S-shape.

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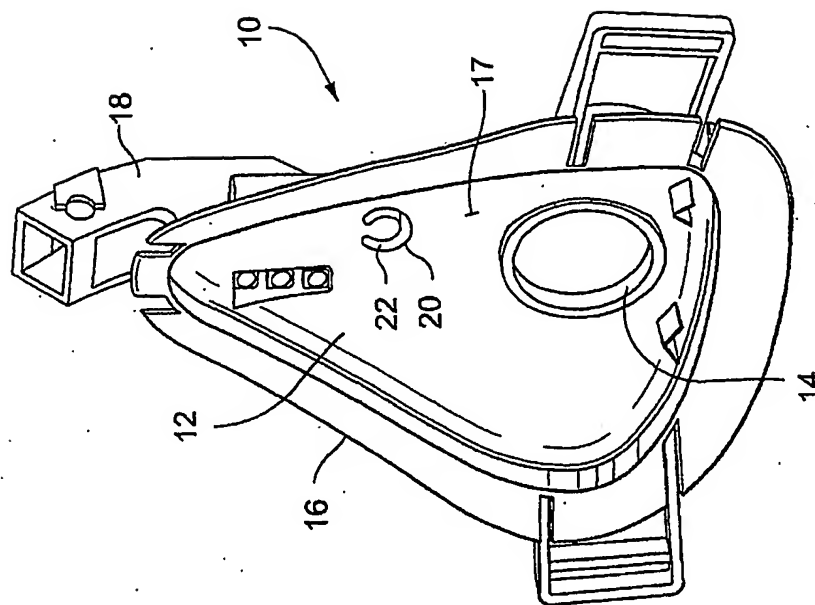


Fig. 2

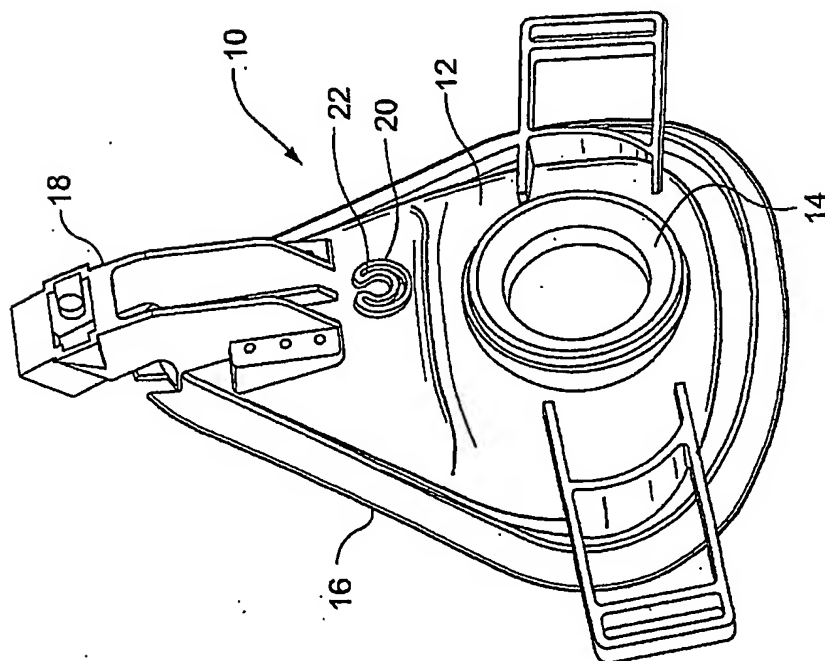


Fig. 1

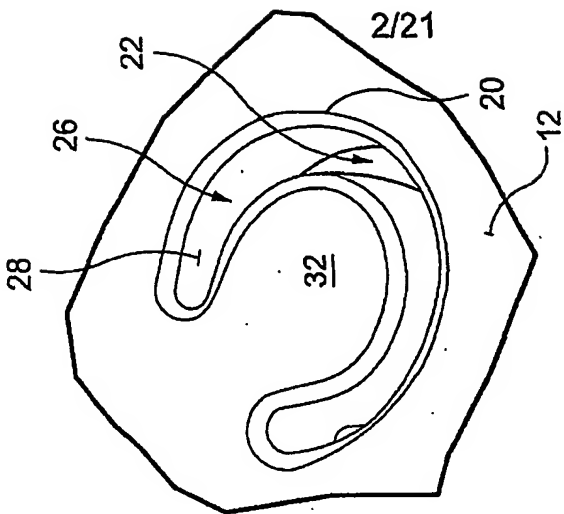


Fig. 5

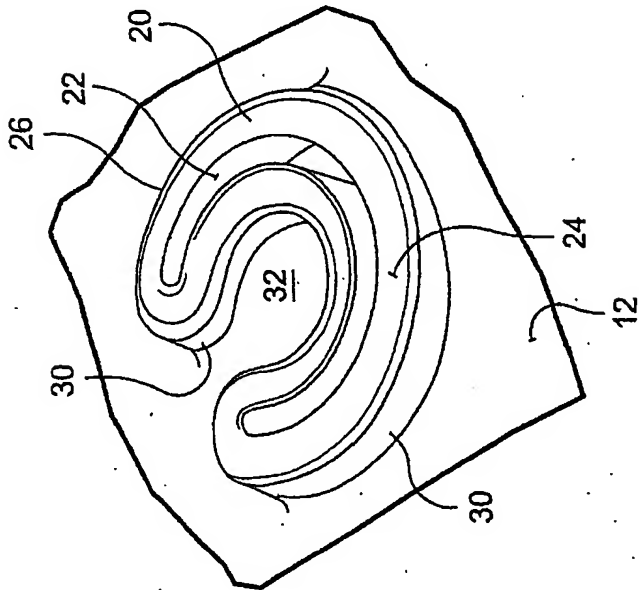


Fig. 4

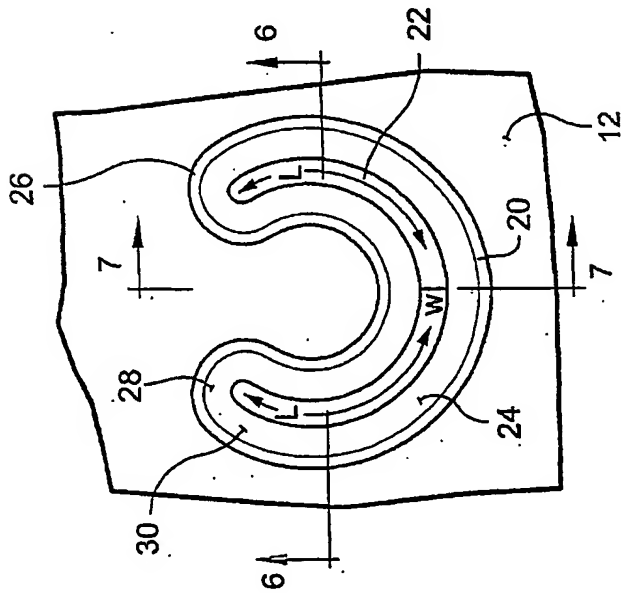


Fig. 3

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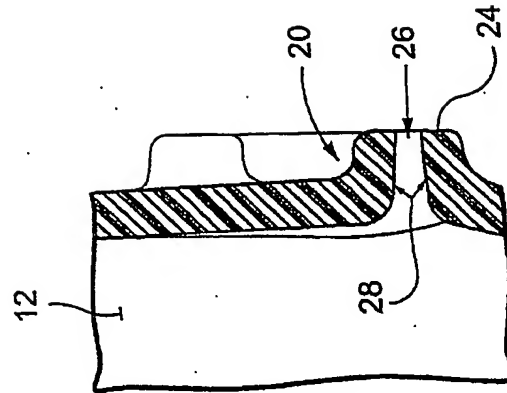


Fig. 7

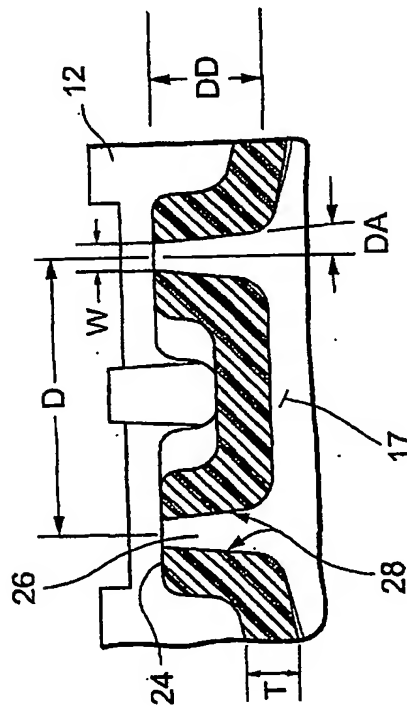


Fig. 6



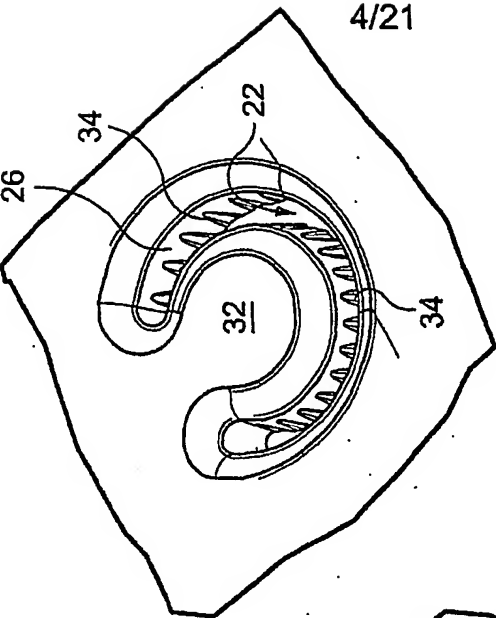


Fig. 10

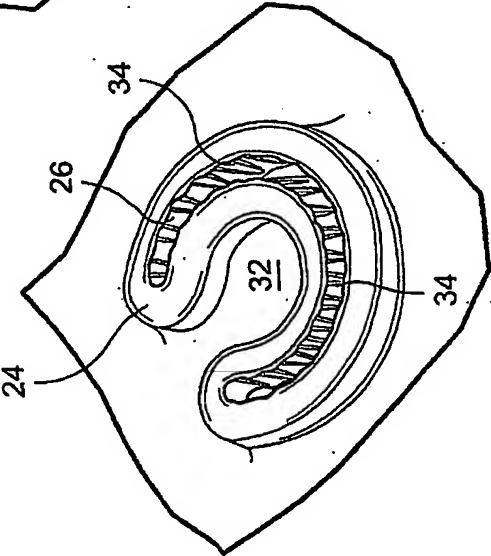


Fig. 9

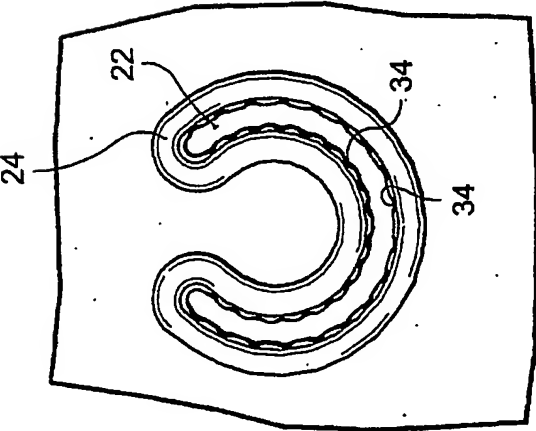


Fig. 8

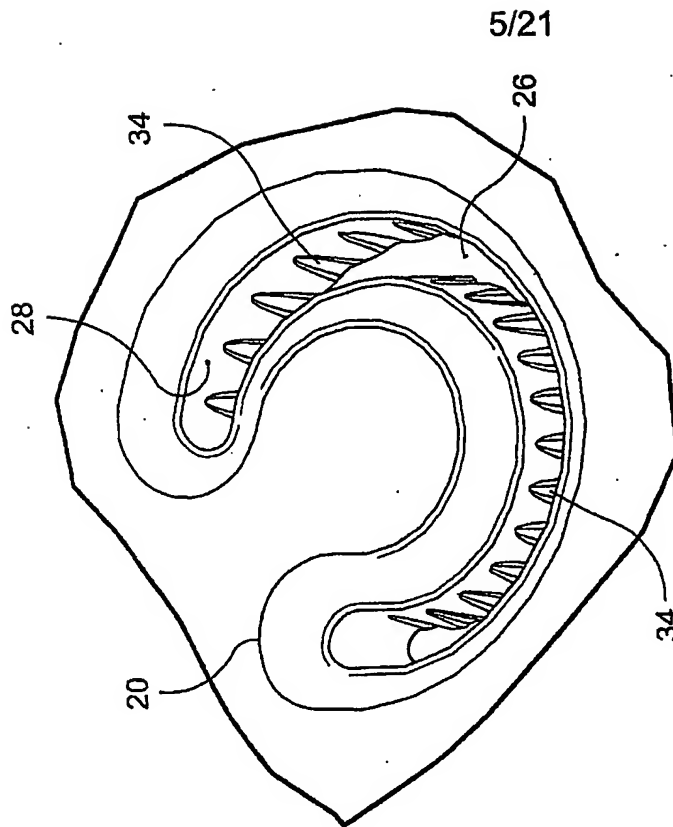


Fig. 12

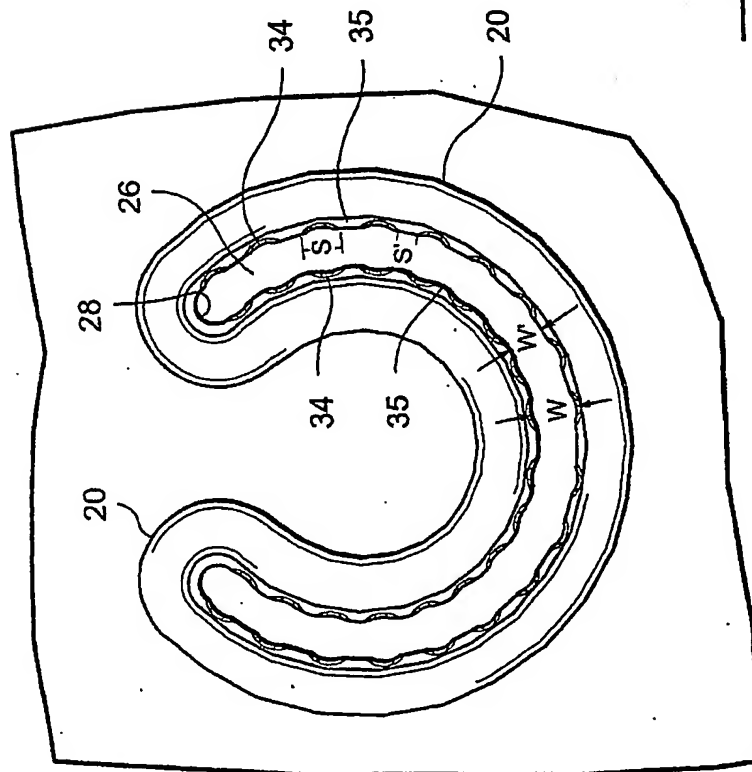


Fig. 11

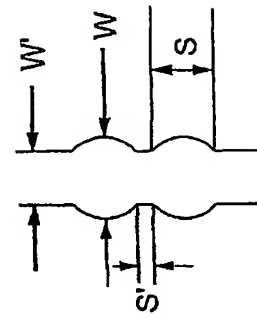


Fig. 11A

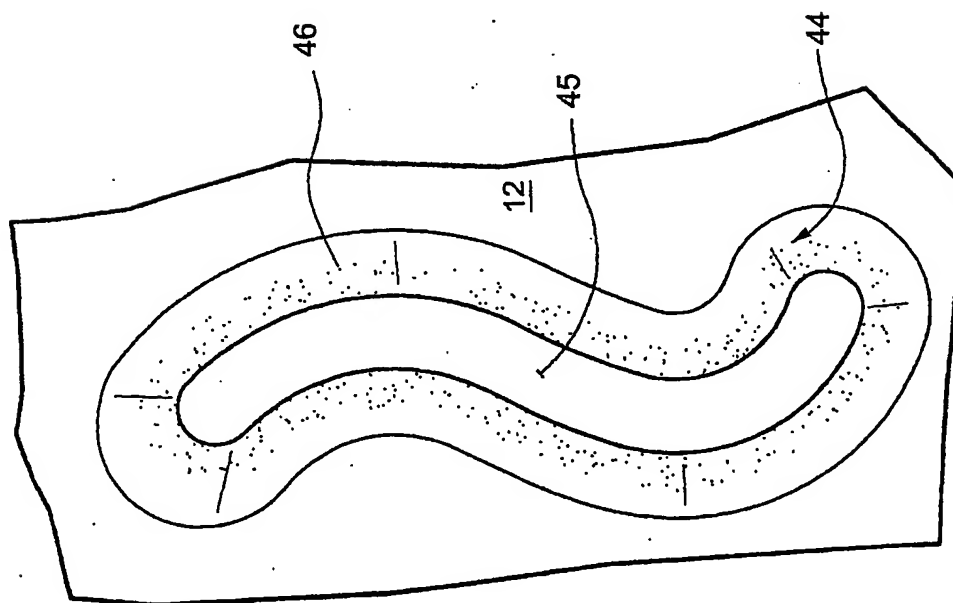


Fig. 13

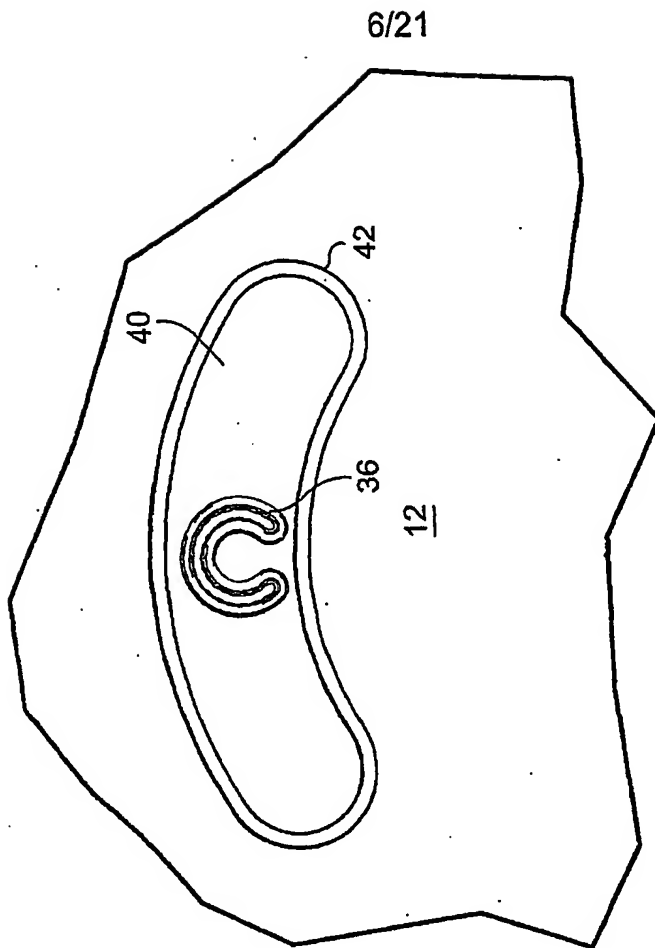


Fig. 14

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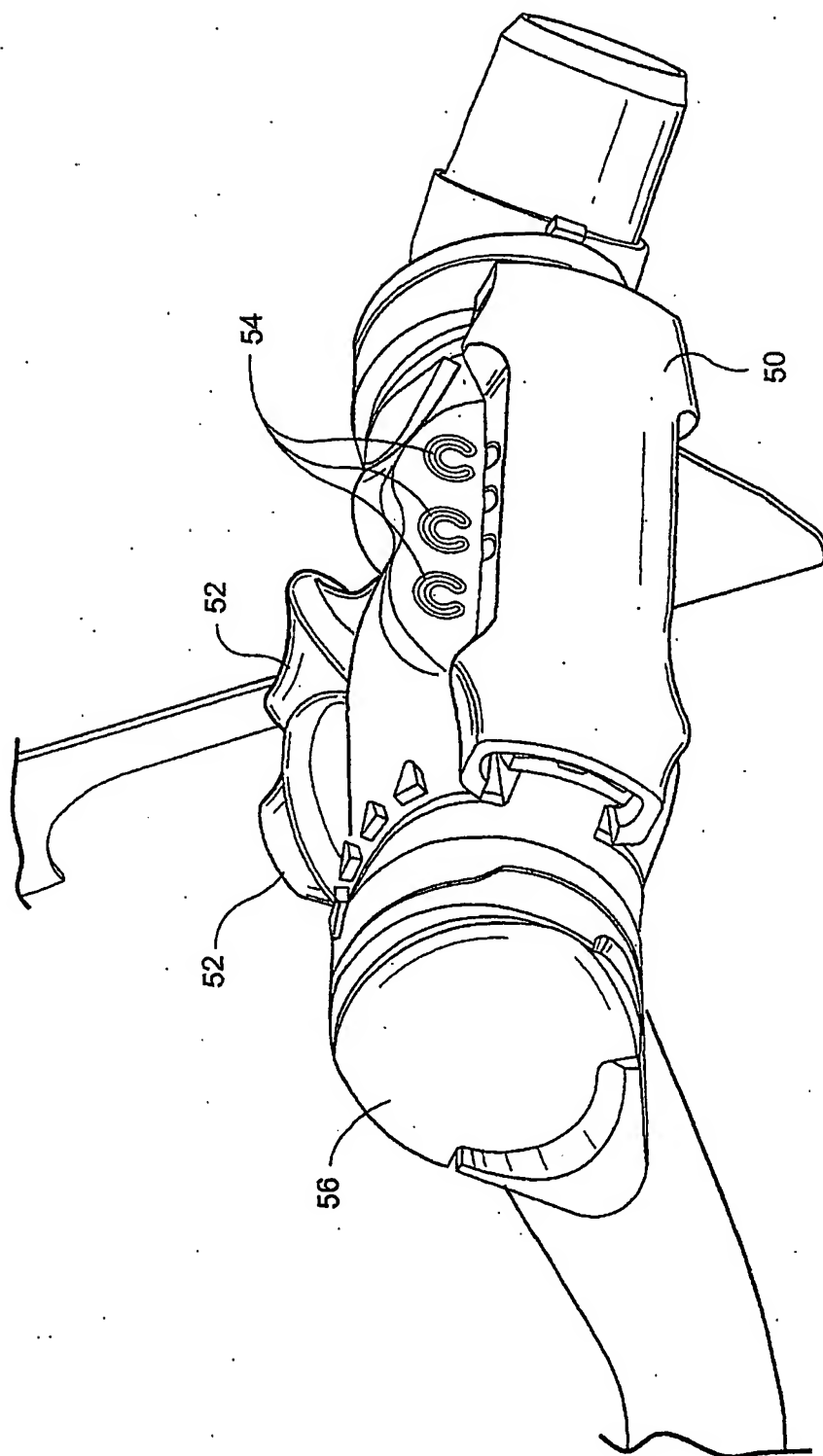


FIG. 15

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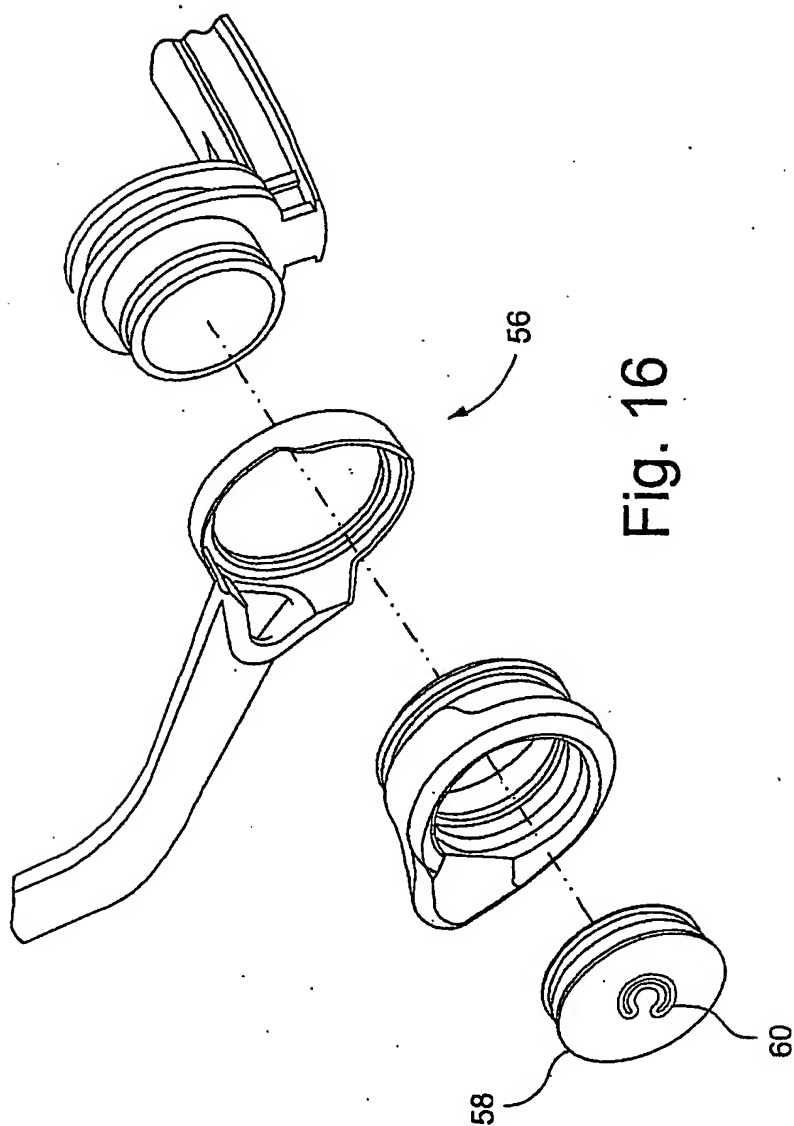


Fig. 16

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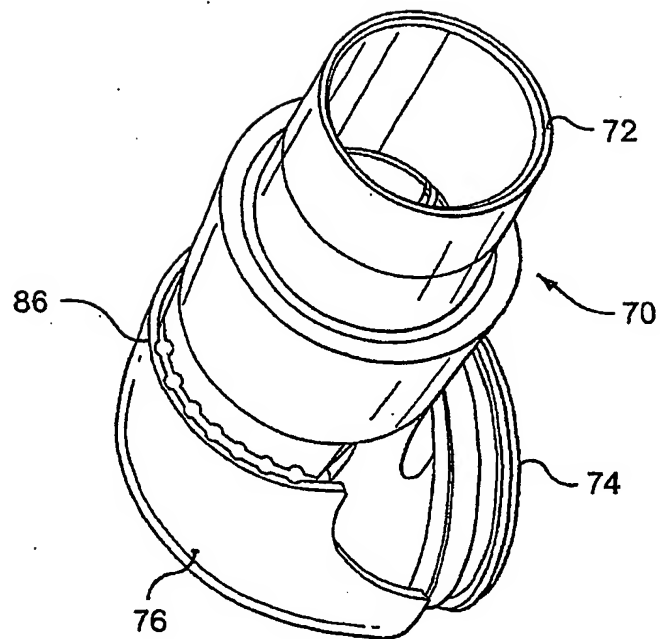


Fig. 17

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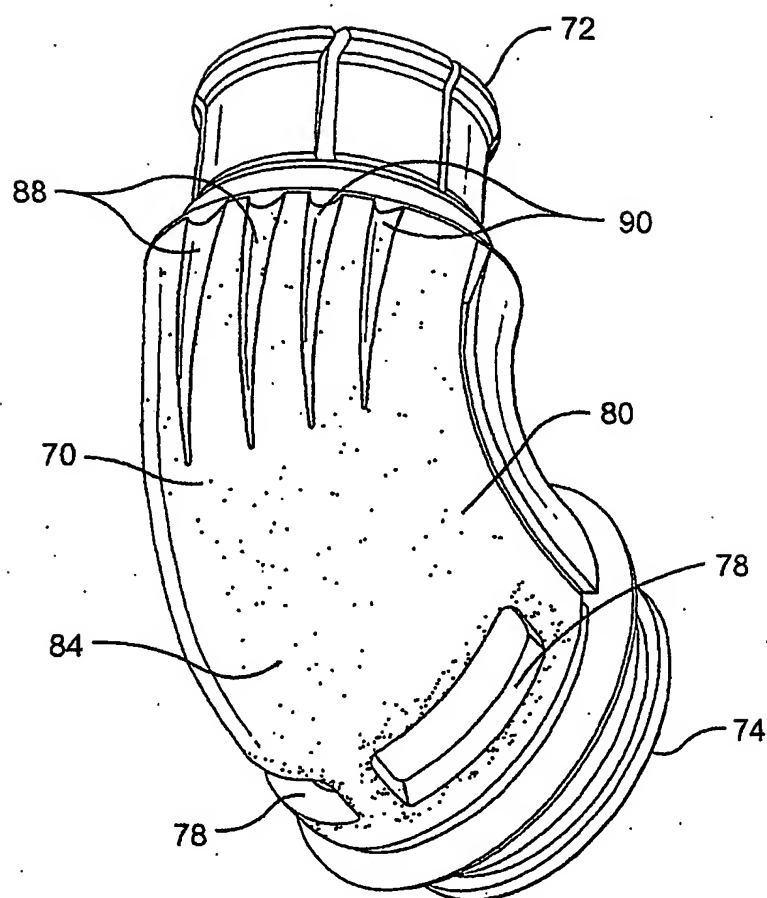


Fig. 18

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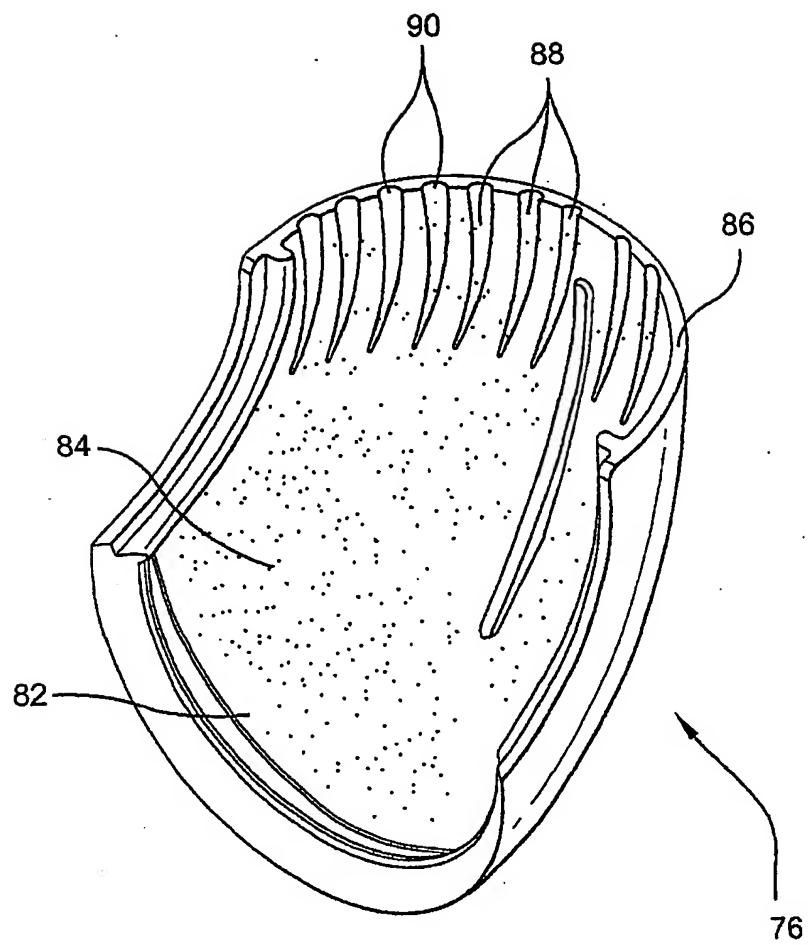


Fig. 19



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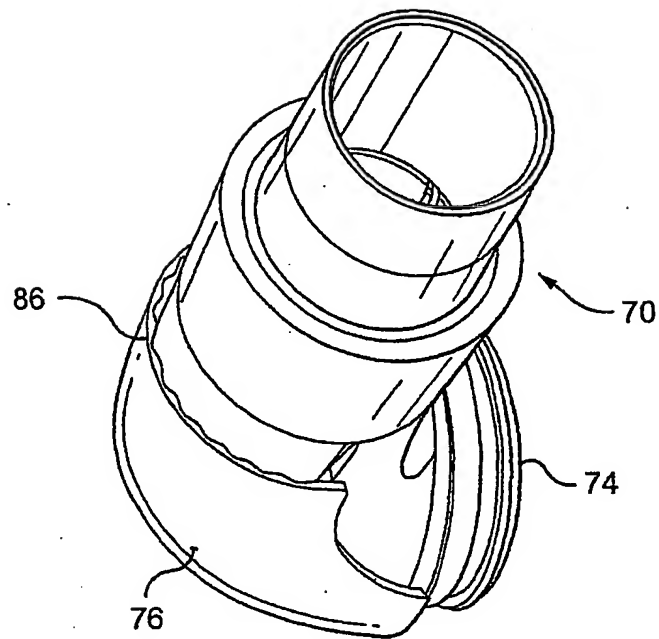


Fig. 20

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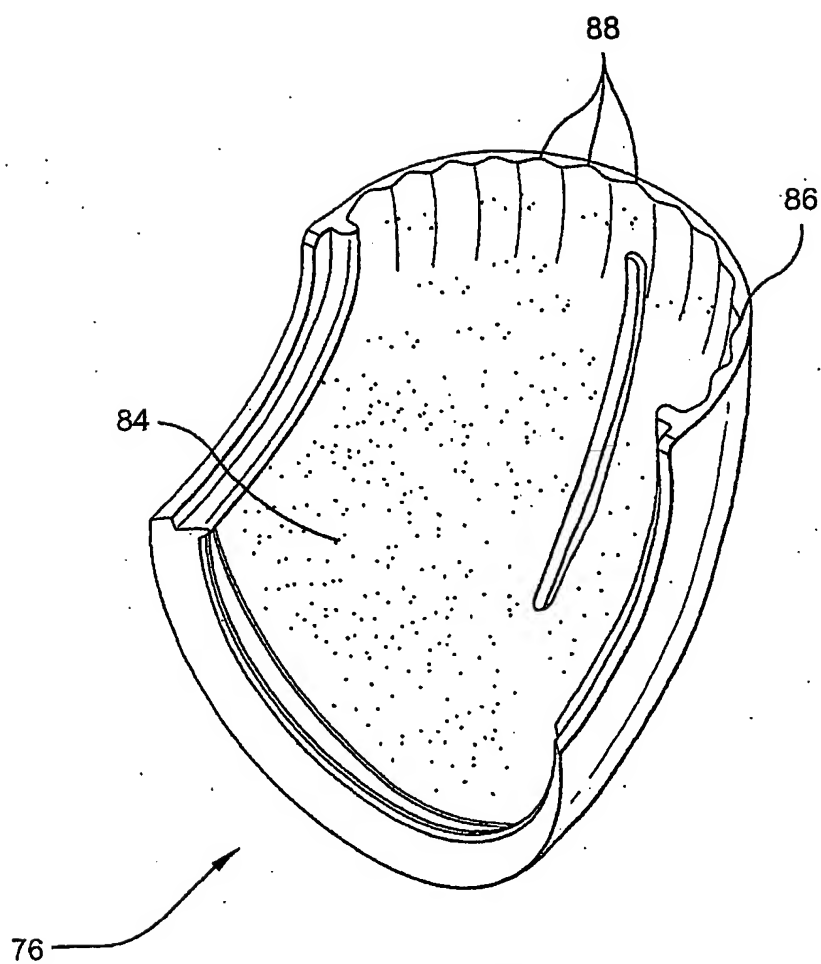


Fig. 21

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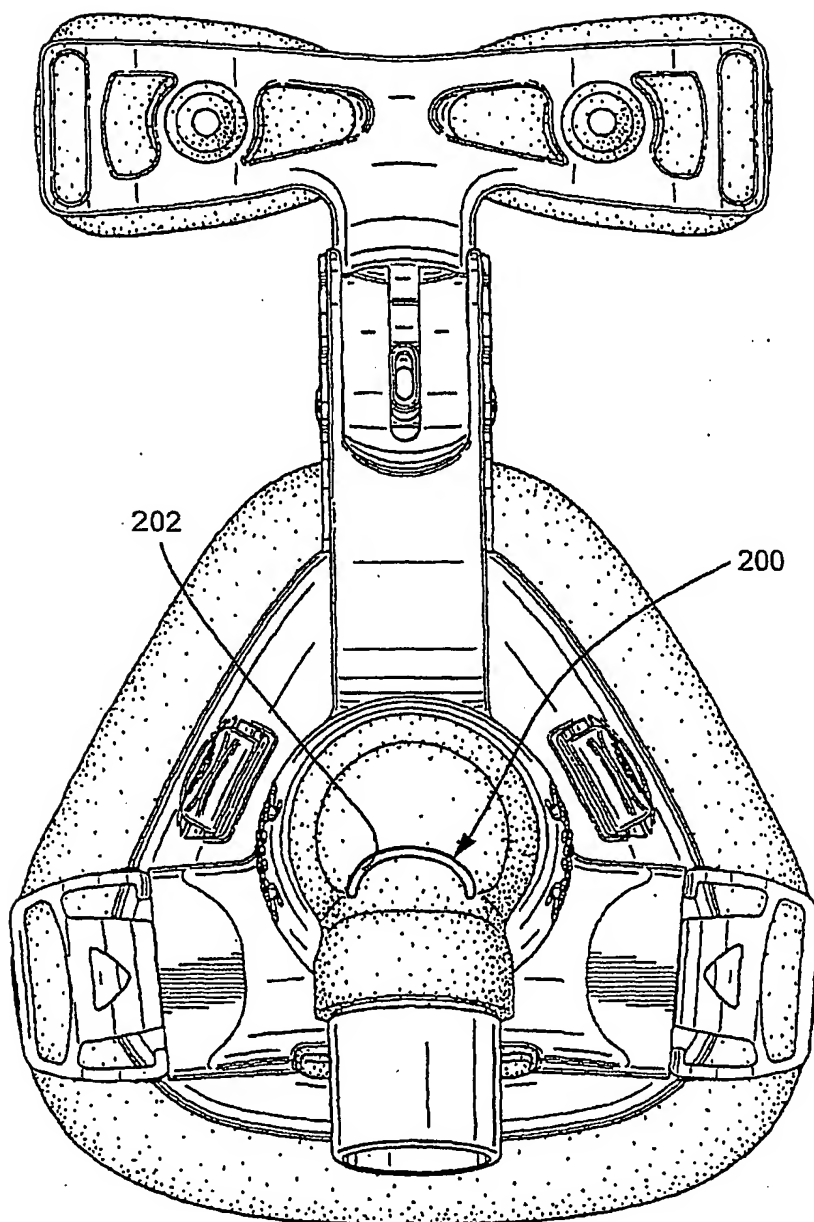


Fig. 22

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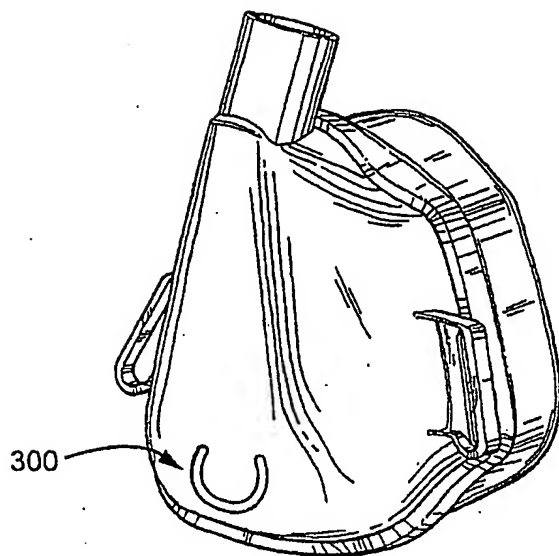


Fig. 23

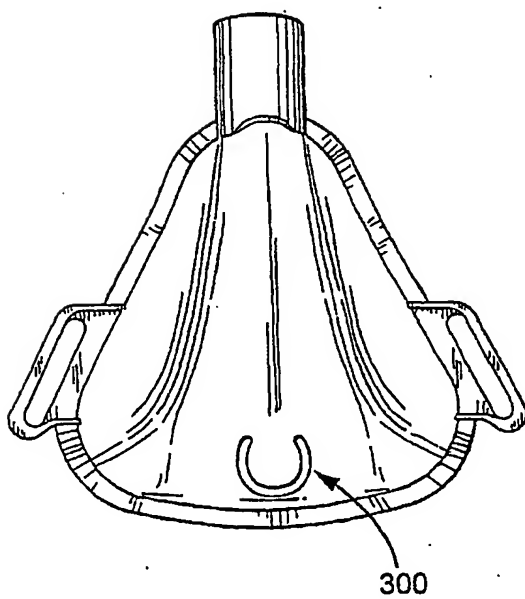


Fig. 24

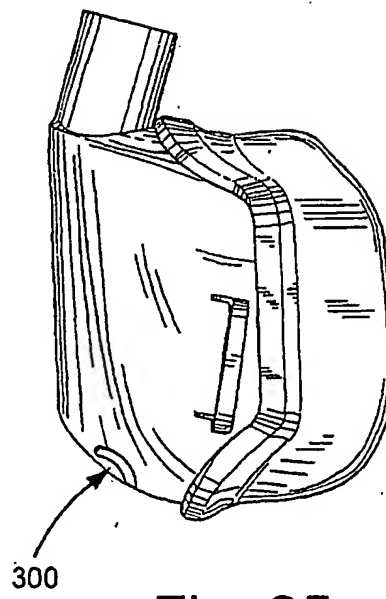


Fig. 25

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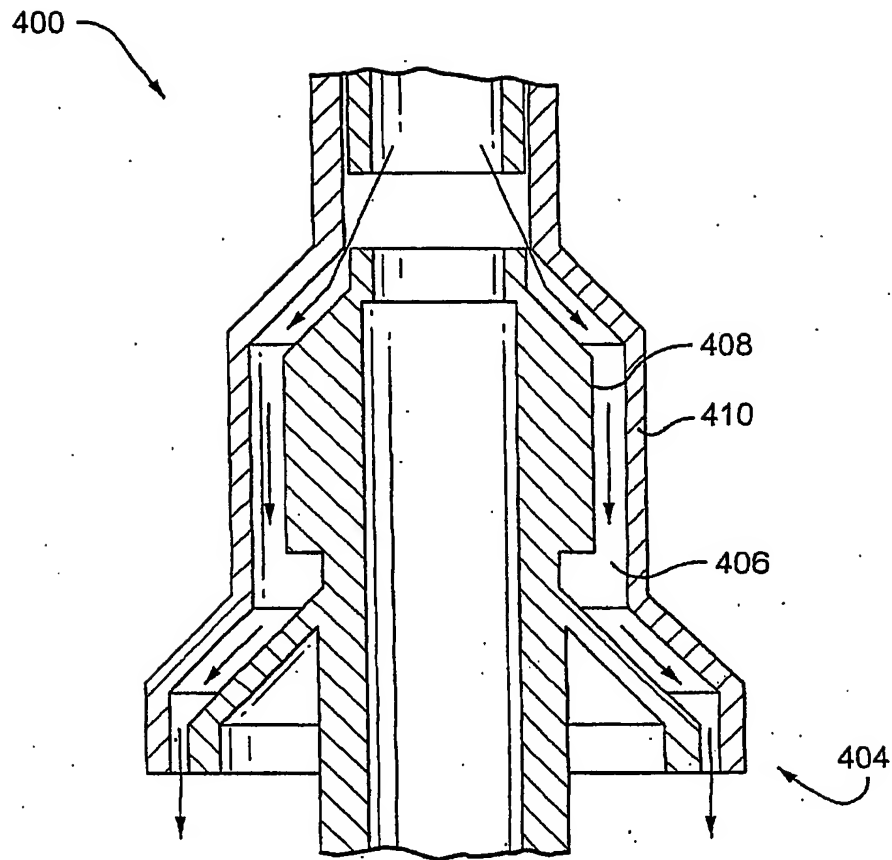


Fig. 26

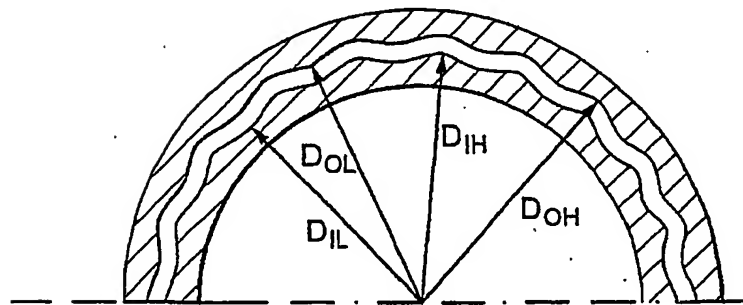


Fig. 27

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Fig. 28

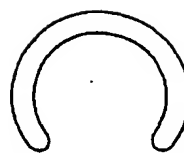


Fig. 29



Fig. 30



Fig. 31

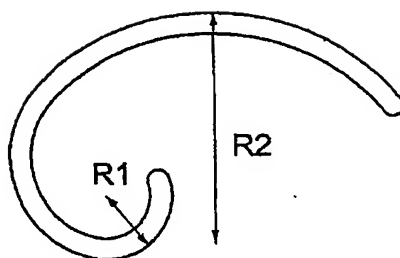


Fig. 32

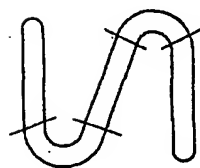


Fig. 33

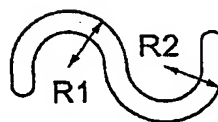


Fig. 34

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Fig. 36

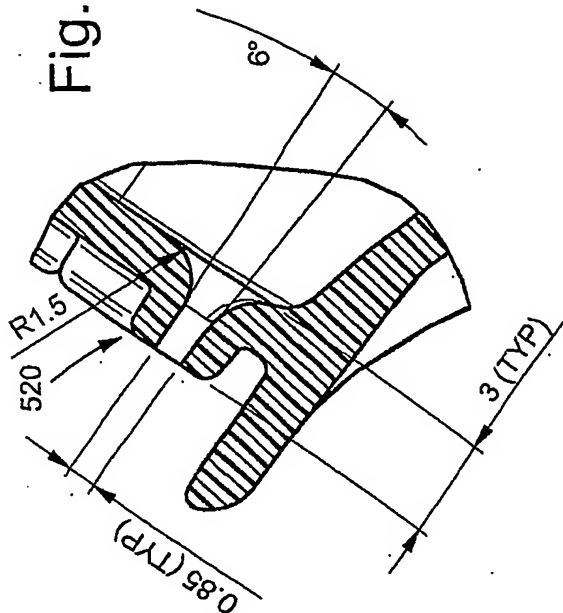
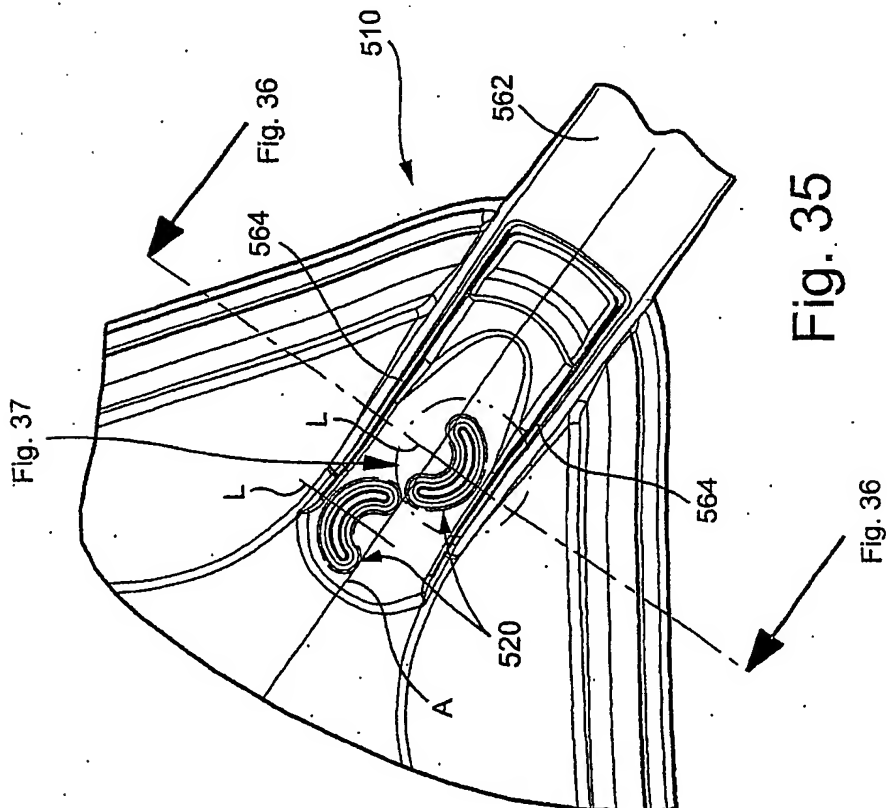
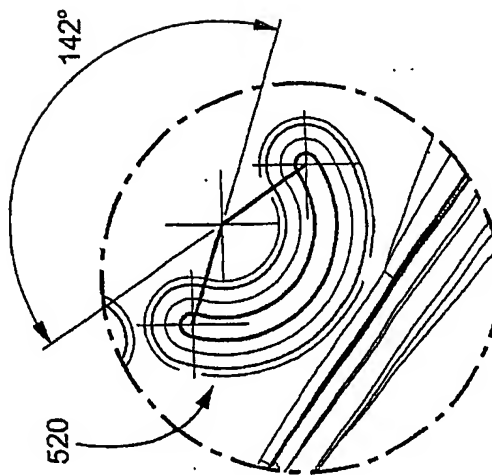


Fig. 37



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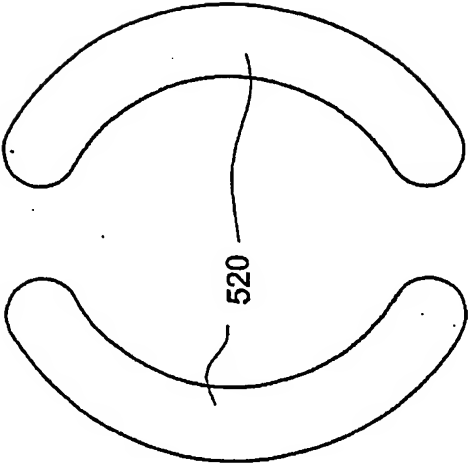


Fig. 40

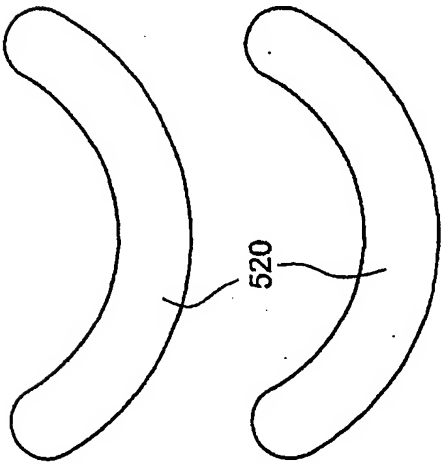


Fig. 39

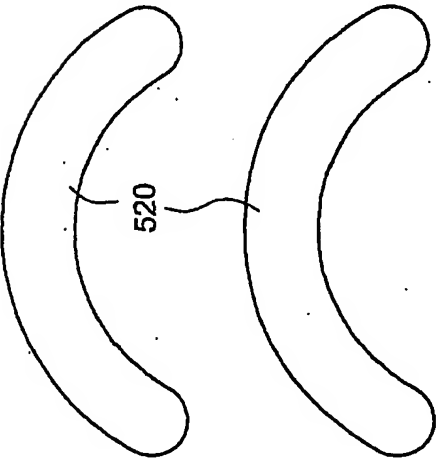


Fig. 38



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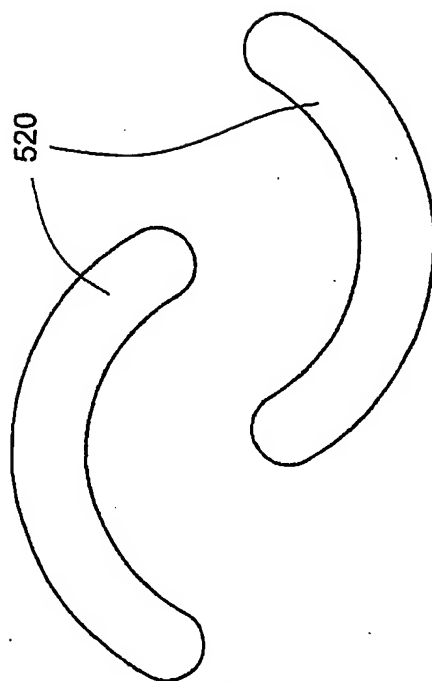


Fig. 42

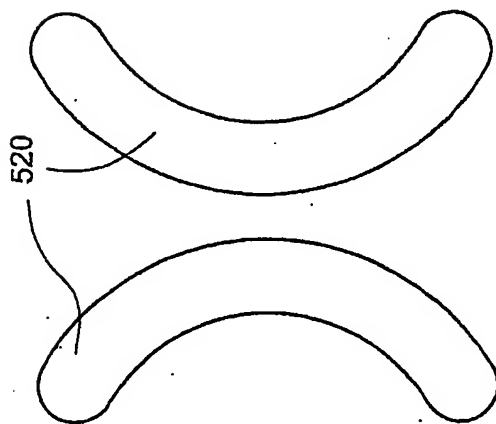


Fig. 41

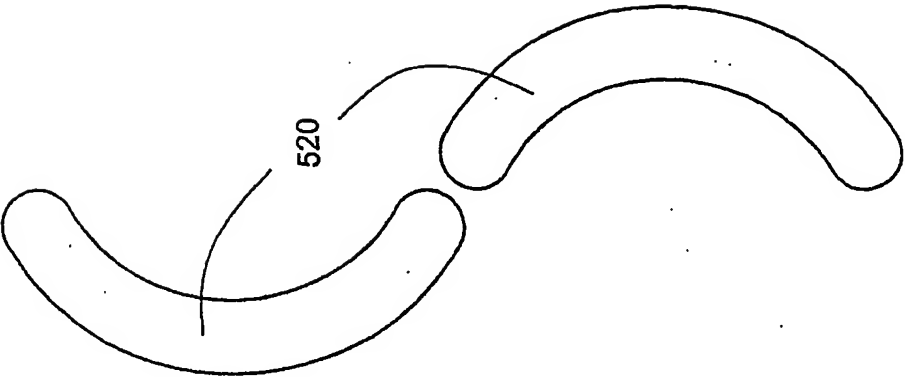


Fig. 44

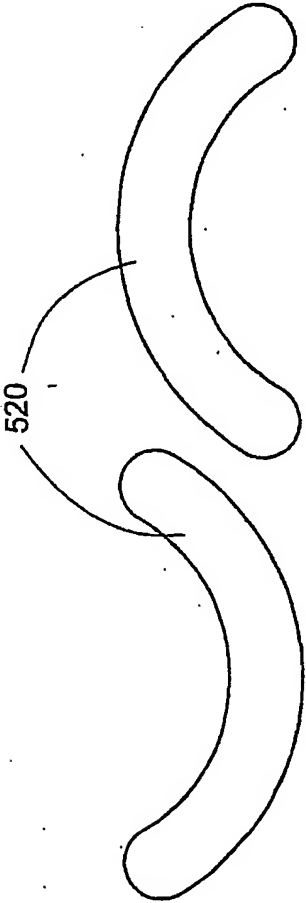


Fig. 43

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/000036

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. *A61M 16/06* (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI and keywords: mask and vent and curve and similar terms

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0005931 A1 (JAFFRE et al.) 9 January 2003 Paragraphs 65 to 76	1-17,23-25, 29-36,50- 57,59-62 40,44,46
A	US 5560354 A (BERTHON-JONES et al.) 1 October 1996 Column 5 lines 35 to 42, figures 1a and 1b	1,4,5,7-12, 14,16,17, 23,29,32-34, 50,51,53-60
X	US 5988160 A (FOLEY et al.) 23 November 1999 Column 3 lines 34 to 45, figure 5	1,4,7,9-17, 23,29,32-34, 50,51,53-61



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  
13 February 2006Date of mailing of the international search report  
- 3 MAR 2006

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Authorized officer

DAVID MELHUISE

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/000036

C (Continuation).

## DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6823865 B2 (DREW et al.) 30 November 2004 Column 4 line 22 to column 6 line 30	1,4-9,11,14, 16,17,22,23, 29-34
X	US 6644316 B2 (BOWMAN et al.) 11 November 2003 Column 2 lines 8 to 18	1,4-9,11,16, 17,19-21, 23-25
X	US 6668830 B1 (HANSEN et al.) 30 December 2003 Column 2 lines 13 to 55	1,4-9,11, 16-24

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2006/000036

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
US	2003005931	BR	0210014	CA	2448445
		US	6851425	EP	1392215
		US	6851425	US	2005126573
		WO	02096342		
US	5560354	AU	48371/97	AU	64816/94
		EP	0634186		
		US	6123071		
US	5988160	AU	50451/93	CA	2102663
		CA	2446608	JP	7000521
		EP	0601708	MX	9306953
		NZ	250105	US	5645049
		ZA	9308360		
US	6823865	US	6581594	US	2003164170
US	6644316	US	2005092326		
		CA	2387228	EP	1221995
		US	2003000532		
		WO	0126722		
US	6668830	NONE			
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					

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